

(1) When the ITC identifies a chemical substance or mixture that it believes should receive expedited consideration by EPA for testing, the ITC may add the substance or mixture to its list of chemicals recommended for testing and include a statement that the ITC intends to designate the substance or mixture for action by EPA in accordance with section 4(e)(1)(B) of the Act.

(2) Chemical substances or mixtures selected for expedited review under paragraph (a)(1) of this section may, at a later time, be designated for EPA action within 12 months of such designation. The ITC's subsequent decision would be based on the ITC's review of TSCA sections 8(a) and 8(d) data and other relevant information.

(3) Where the ITC concludes that a substance or mixture warrants testing consideration but that expedited EPA review of testing needs is not justified, the ITC will add the substance or mixture to its list of testing recommendations without expressing an intent to designate the substance or mixture for EPA action in accordance with section 4(e)(1)(B) of the Act.

(4) The ITC reserves its right to designate any chemical that it determines the Agency should, within 12 months of the date first designated, initiate a proceeding under section 4(a) of the Act.

(b) *EPA consideration of ITC recommendations.* (1) Where a substance or mixture is designated for EPA action under section 4(e)(1)(B) of the Act, the Agency will take either one of the following actions within 12 months after receiving the ITC designation:

(i) Initiate rulemaking proceedings under section 4(a) of the Act.

(ii) Publish a FEDERAL REGISTER notice explaining the Agency's reasons for not initiating such rulemaking proceedings. EPA may conclude that rulemaking proceedings under section 4(a) of the Act are unnecessary if it determines that the findings specified in section 4(a) of the Act cannot be made or if the Agency has entered into a consent agreement requiring testing in accordance with the provisions of this subpart.

(2) Where a substance or mixture has been recommended for testing by the

ITC without an intent to designate, EPA will use its best efforts to act on the ITC's recommendations as rapidly as possible consistent with its other priorities and responsibilities. EPA may respond to the ITC's recommendations either by:

(i) Initiating rulemaking proceedings under section 4(a) of the Act.

(ii) Publishing a FEDERAL REGISTER notice explaining the Agency's reasons for concluding that testing is unnecessary.

(iii) Entering into a consent agreement in accordance with this subpart.

**§ 790.22 Procedures for gathering information and negotiating consent agreements on chemicals which the ITC has recommended for testing with an intent to designate.**

(a) *Preliminary EPA evaluation.* Following receipt of an ITC report containing a recommendation with an intent to designate, EPA will use the following procedure for completing a preliminary evaluation of testing needs. Appendix A<sup>1</sup> to this part presents the schedule that EPA intends to follow for this purpose.

(1) EPA will publish the ITC report in the FEDERAL REGISTER and announce that interested persons have 30 days to submit comments on the ITC's testing recommendations.

(2) EPA will publish a FEDERAL REGISTER notice adding all ITC-recommended chemicals to the automatic reporting provisions of its rules under sections 8(a) and 8(d) of the Act (40 CFR parts 712 and 716).

(3) EPA will hold a public "focus meeting" to discuss the ITC's testing recommendations and obtain comments and information from interested parties.

(4) EPA will evaluate submissions received under the sections 8(a) and 8(d) reporting requirements, comments filed on the ITC's recommendations, and other information and data compiled by the Agency.

(5) EPA will make a preliminary staff determination of the need for testing and, where testing appears warranted, will tentatively select the studies to be performed.

<sup>1</sup>Editorial Note: Appendix A appears at the end of subpart E.

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(6) EPA will hold a public meeting to announce its preliminary testing determinations.

(b) *Negotiation procedures for consent agreements.* Where EPA believes that testing is necessary, the Agency will explore whether a consent agreement can be negotiated that satisfies the testing needs identified by the Agency. EPA will use the following procedures for negotiating, formulating and accepting consent agreements. Appendix A<sup>1</sup> to this part presents the schedule that EPA intends to follow for this purpose.

(1) In the FEDERAL REGISTER notice described in paragraph (a)(1) of this section, EPA will explain its procedures and timetable for negotiating consent agreements and invite persons interested in participating in or monitoring negotiations to contact the Agency in writing.

(2) Persons who respond to EPA's notice by the announced date of the Agency's course-setting meeting will be deemed "interested parties" for purposes of any negotiations that EPA conducts.

(3) Following the course-setting meeting announcing EPA's preliminary testing determinations, the Agency will meet with manufacturers, processors and other interested parties for the purpose of attempting to negotiate a consent agreement. To facilitate attendance at these meetings, EPA will contact all interested parties who have expressed a desire to participate in or monitor negotiations under paragraph (b)(2) of this section and advise them of meeting dates.

(4) All negotiating meetings will be open to members of the public. The minutes of each meeting will be prepared by EPA. Meeting minutes, testing proposals, background documents and other materials exchanged at or prepared for negotiating meetings will be included in the public file established by EPA on each ITC-recommended chemical. Materials in this file will be made available for inspection in the OPPTS Reading Room during EPA working hours.

(5) While negotiations are underway, EPA will promptly circulate meeting minutes, testing proposals, correspondence and other relevant materials to

interested parties who expressed a desire to participate in or monitor negotiations pursuant to paragraph (b)(2) of this section.

(6) As negotiations progress, EPA will make a tentative decision either to proceed with formulation of a consent agreement or to initiate rulemaking. EPA will terminate negotiations after 10 weeks and proceed with rulemaking unless negotiations are likely to result in a draft consent agreement within 4 additional weeks. By the end of this 4-week period, EPA either will have prepared a draft consent agreement reflecting the apparent consensus of the parties or will terminate negotiations and proceed with rulemaking. If EPA decides to proceed with rulemaking, no further opportunity for negotiations will be provided. EPA will promptly send written notice to all interested parties of the termination of negotiations.

(7) Where EPA prepares a draft consent agreement, it will be circulated for comment to all interested parties who expressed a desire to participate in or monitor negotiations under paragraph (b)(2) of this section. A period of 4 weeks will be provided for submitting comments or written objections under § 790.24(a).

(8) If necessary, EPA will hold a public meeting to discuss comments on the draft consent agreement and to determine whether revisions in the agreement are appropriate.

(9) Where a consensus exists concerning the contents of a draft consent agreement, it will be circulated to EPA management and interested parties for final approval and signature.

(10) Upon final approval of a consent agreement, EPA will publish a FEDERAL REGISTER notice that summarizes the agreement, describes the ITC recommendations for the test substance, outlines the chemical's use and exposure characteristics, and explains the background, objectives and rationale of the testing to be conducted, and codifies in subpart C of part 799 the name of the substance(s) to be tested and the citation to the FEDERAL REGISTER notice of the agreement.